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12/18/01  
10023095-121301  
jc698 U.S. PTO

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marian L. Kruzel

Title: TREATING COMPOSITIONS  
WITH LACTOFERRIN

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Group Art Unit:

Examiner:

Attorney docket

No.: FDI004

PRELIMINARY AMENDMENT TO DECLARE AN INTERFERENCE

WITH U.S. 6,172,040

Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Sir:

Applicant has copied claims of U.S. 6,172,040 and it's application file for the Examiner to declare an interference.

Claim 1 herein is Claim 1 as filed in Serial No. 09/322,700, upon which U.S. 6,172,040 is based. The Examiner rejected claim 1 as filed in Serial No. 09/322,700 in the Office Action of 12/30/99 (§ 7) and in the Office Action of 04/21/2000 (§ 3) stating: "Claim 1 is rejected under 35 U.S.C. 103(a) as being obvious over Tomita et al. (U.S. Patent No. 5,656,591) in view of Collison et al. or Wiloit." As to Applicant's claim 1, none of these patents are effective since their dates of filing are all after Applicant's filing of his parent application on March 3, 1990, the effective date of this application. (Front pages provided as Attachment 1). Therefore Claim 1 herein is patentable to Applicant and should be allowed.

The basis for each claim presented herein is found in Applicant's specification as follows:

Claim	Words of Differentiation	Page and line of specification
1		Page 3, lines 13-23 Page 9, lines 7-14 Page 14, lines 2-4 and lines 7-8
2	isolated	Page 3, lines 2-12 Page 14, lines 22-25 Page 26, lines 6-7
3	mixed with a substrate	Page 9, lines 7-14
4	naturally occurring substrate	Page 9, lines 11-14 Page 13, lines 13-21

The specifics of Applicant's disclosure are that human recombinant lactoferrin is produced by expression in *Pichia pastoris*. For example, the expression and purification of the lactoferrin is illustrated in Example 15 on page 25, line 21 to page 27, line 3. On page 26, lines 6 and 7 it states: "The lactoferrin is isolated and concentrated from the growth media in one step chromatography". (emphasis added) Further, on page 14, lines 22-25, it states: "The lactoferrin contemplated for use in accordance with the present invention is preferably of human origin, more preferably via DNA recombinant means, but other lactoferrins, such as natural bovine, goat and porcine lactoferrin, isolated and purified using methods applicable to natural lactoferrin, are contemplated."

(emphasis added) The basis of "isolated" lactoferrin is present in the present application as set forth above.

The present application discloses the use of lactoferrin as an antiseptic, specifically the growth of microbes, such as bacteria on page 9, lines 7-14. Specifically, it is stated on page 9, line 11 et seq: "Preferable antiseptics of the present invention include lactoferrin either alone or compounded with carriers such as saline, silica, talcum, stearic acid, its magnesium or calcium salt, polyethyleneglycol, and fatty emulsions and suspensions that will be readily apparent to the skilled artisan." The patentee states: "The LF is immobilized on the substrate using any suitable technique." (Col.4, lines 2-24) Simply mixing the lactoferrin and the substrate results in the lactoferrin being "immobilized on the substrate" according to the patentee. Thus, applicant's mixing of lactoferrin with carriers and patentee mixing with substrates, where the carrier and substrate are identical results in identical compositions however expressed. The two words, carrier and substrate, having identical meaning in the context of their respective disclosures. Similarly, "mixed with or compounded with" as used in the present application is identical to "immobilized on" as used by the patentee. Accordingly, claim 4 herein is directed to the identical invention as claimed in Claim 1 of 6,172,040.

The only reference found in Patent U.S. 6,172,040 regarding "N-terminus" is in column 4, lines 5-8 where it states: "The LF is immobilized on a naturally occurring substrate. Such substrates include organic compounds, which attach to the LF protein to the N-terminus." Included in the list of compounds in col.4, lines

7-19 is "cellulose". The present application discloses cellulose (page 13, line 18) and other naturally occurring substrates or adjuvant or diluent. The disclosure of cellulose in the present application is a natural occurring "substrate" and is an organic compound just as the disclosure of cellulose in the patent. The binding or immobilization is inherent that the lactoferrin will be "via the N-terminus of the lactoferrin". Hence, the description "via the N-terminus of the lactoferrin" has no distinction in fact and certainly is not a patentable distinction over the disclosure of the present application.

Claims 8-11 herein are directed to a method "for reducing the microbial contamination of a composition subject to microbial contamination" rather than "a meat product".

Claim 12 is the claim in the original application of Applicant; namely, Serial No. 07/489,186, filed March 8, 1990.

Claim 4 in the present application is the identical invention of claim 1 of U.S. 6,172,040 and claim 10 or 11 herein is the identical invention of claim 45 of U.S. 6,172,040; however, "isolates" in claim 45, line 4 is believed to be in error and should be isolated.

One count of the interference, as regard to the inventions set forth in claims 1-7 herein and claim 1 of U.S. 6,172,040, should be claim 1 which defines the invention as follows:

"A method for reducing the microbial contamination of a meat product, comprising treating the meat product with a sufficient amount of lactoferrin to reduce microbial contamination."

A second count of the interference, as regard to the inventions set forth in claims 8-11 herein and claim 45 of U.S. 6,172,040, should be claim 8 which defines the invention as follows:

“A method for reducing the microbial contamination of a composition subject to microbial contamination comprising treating the composition with a sufficient amount of lactoferrin to reduce microbial contamination.”

37 CFR § 1.606 states: “At the time an interference is initially declared (§1.611), a count shall not be narrower in scope than any application claim that is patentable....” Applicant has shown that the effective date of this application, March 8,1990, is prior to the dates of the references used to reject claim 1 as presented by the patentee. Claims 2-7 herein are narrower claims to the same invention and claim 1 of U.S. 6,172,040 are directed to the same invention using different words having no significant patentable meaning. That there is interfering subject matter between Applicant and Patentee is that proposed count one is identical to claim 1 filed in Serial No. 09/322,700, which matured into U.S. 6,172,040.

37 CFR §1.607 states that “An applicant may seek to have an interference declared between an application and an unexpired patent by:”

- (1) Identifying the patent. The patent is U.S. 6,172,040, granted January 9, 2001, entitled “Immobilized Lactoferrin Anticicrobial Agents and the Use Therof”, based on Serial No. 09/322,700, filed May 28,1999, inventor and assignee A. Satyanarayan Naidu.

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- (2) Presenting a proposed count. Herein above two counts are proposes, corresponding to claims 1 and 8 of this application.
  - (3) Identifying at least one claim in the patent correspoding to the proposed count. Claim 1 of the patent corresponds to count one and claim 45 corresponds to count two.
  - (4) Presenting at least one claim corresponding to the proposed count.....  
Claim 1 herein is count one and claim 8 is count two.
  - (5) Applying the terms of any application claim,... The terms used in the proposed counts are found in the present application and the patent and require no resolution of meaning.
  - (6) No explanation necessary. This application is filed before one year of the issue of U.S. 6,172,040.

All the requirements of 37 CFR §1.607 having been met, an interference between the present application and U.S. 6,172,040 is respectfully requested.

Respectfully submitted,



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